Statement of Christina Cherel, Program Coordinator, National Women's Health Network

November 4, 2015

Food and Drug Administration Meeting of the Division of Bone, Reproductive, and Urologic Products in the Center for Drug Evaluation and Research:

"Osteoporosis Drug Development: Moving Forward"

My name is Christina Cherel, and I am the Program Coordinator at The National Women's Health Network. The National Women's Health Network is a nonprofit advocacy organization that works to improve the health of all women. We are supported by our members and by choice, we do not accept financial support from drug companies or medical device manufacturers. We bring the voices, concerns and needs of women consumers to policy and regulatory tables.

Since the Network's founding 40 years ago, we have brought the voices of women to the FDA, advocating for medical products that meet women's real life needs and a drug development process that reflects women's lived experiences.

We are pleased to have the opportunity today to comment on the clinical development of drugs and biologics intended to treat osteoporosis. The Network has followed this issue area for over thirty years and previously testified regarding the approval of drugs intended to prevent osteoporosis. As such, we respectfully submit the following for consideration by the FDA.

Osteoporosis is a disease, more common in women, that causes bones to become fragile and more susceptible to breaking. Fractures and the consequent pain and disability can seriously affect women's health and their quality of life. Some women — most commonly those who don't have good access to health care — experience fractures that could have been prevented if their osteoporosis had been treated.

In the 1980s, women's health advocates, including the Network, were concerned that the medical community had overlooked the effect of bone fractures on older women's quality of life. The Network envisions a world where women are able to live independently throughout their lives, with as little as frailty as possible. We advocated for change — and were successful in our

efforts. Forty years ago osteoporosis was underdiagnosed and undertreated. That is no longer the case, and that's cause for celebration. But unfortunately, today, it seems, the pendulum has swung to the other extreme. Too often, healthy women at very low risk of fracture are given a diagnosis and urged to begin treatment.

It may seem odd to bring up the issue of overdiagnosis and overtreatment in a workshop that is part of the FDA's effort to accelerate patient access to new medical treatments. What does overdiagnosis and overtreatment have to do with that effort? We think that it's very important for the FDA and its advisors to consider the possible implications of these issues as it considers how to use surrogate markers in future guidelines for the development of osteoporosis drugs. We also recommend that the FDA and its advisors think carefully about the targeted populations for prevention.

The Network supports the continued development of safe and effective osteoporosis drugs. More effective treatments for women suffering from the often debilitating effects of clinical osteoporosis would be an important advance. The Network, however, also recognizes that drugs used in healthy women to prevent osteoporosis require special indications and labeling. Basing the indication for prevention primarily or solely on Bone Mineral Density (BMD) scanning alone, needs to be rethought in order to maximize benefit and minimize harm to women. When the FDA initially approved bisphosphonates for preventing osteoporosis, this was based on the best science available at the time. The Network believes that the information available today should lead to a different conclusion, especially about long-term use and the indication for prevention.

When bisphosphonates were first proposed as a treatment for osteoporosis, we supported the goal of providing women with an alternative to hormone therapy. The Network also cautioned that not enough was known about the drug's long term effects, and unfortunately many of those concerns have been borne out. There have been numerous reports of women who use bisphosphonates having unusual bone fractures that take longer than normal to heal. Some women report experiencing severe bone, joint, and muscle pain after starting to use a bisphosphonate. These injuries, while relatively rare, often occur in otherwise healthy women, most of whom would have never developed osteoporosis.

The FDA states that they believe that women at low risk of fracture should consider stopping bisphosphonates after three to five years because of these problems. NWHN believes that it is also very important for women to carefully consider whether or not to start these drugs in the first place. We have asked the FDA to reconsider the use of these drugs for prevention, based on our concern that many women are experiencing complications from these drugs with little to no chance of benefit. Indicating bisphosphonate use for prevention as well as treatment of

osteoporosis meant that women began using these drugs at younger ages and may continue to use them for decades.

Research is needed on both osteoporosis and the use of DEXA scans for women of color, and until such research has been conducted we recommend that women of color approach screening with even more caution. There must be a better approach to treating women at risk for developing osteoporosis.

The National Women's Health Network strongly supports the development of safe and effective options for treating osteoporosis. As the FDA considers updating its guidelines to accelerate patient access to new treatments for osteoporosis, we urge you take into consideration the problems that can come about as a result of using surrogate markers, the need for more research on women of color, and the need to think very carefully about targeting populations for prevention. Creating guidelines that represent the highest quality of science and rigor will improve women's health.

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